MANAGEMENT OF SPECIALTY DRUGS, SPECIALTY PHARMACIES, AND BIOSIMILARS IN THE UNITED STATES

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The TPG-National Payor Roundtable (TPG-NPRT) focuses on market access programs within the United States, is a subsidiary of The Pharmacy Group, and maintains a database of Chief Medical Officers and Chief Pharmacy Officers in the United States.

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BACKGROUND

- Specialty Pharmacy (SP) products:
  - Treat specific, complex, and chronic diseases
  - Are costly, require reimbursement, have handling assistance & training, have unique and limited distribution processes, and frequently have patient-adherence programs
- Based on the 12 months ending June 2018, Specialty Pharmaceutical[1]:
  - Expenditures continue to grow and reached 44.5% of the non-discounted spending during this period (up from 31.5% in 2013)
    - The top specialty products (rank, sales in billions) include: Humira (#1, $17.5), Remicade (#2, $8), Enbrel (#3, $5.4)
  - Products are often biologic agents and seven of the top 20 specialty products have biosimilar products in the market or in development
- Currently in the US Market: 18 biosimilars have been approved since 2015, only 7 products are marketed, representing biosimilars of[2,3]:
  - Neupogen® (Filgrastim): marketed as Zarxio® by Sandoz and as Nivestym™ by Pfizer
  - Remicade® (Infliximab): marketed as Inflectra® by Celltrion/Pfizer and as Renflexis® by Samsung Bioepis/Merck
  - Epogen® (Epoetin): marketed as Retacrit® by Pfizer
  - Neulasta® (Pegfilgrastim): marketed as Fulphila™ by Biocon/Mylan and as Udenyca™ by Coherus
- Based on recent programs with US payors, Medical Directors and sponsors (pharmaceutical, medical device, and health technology companies), the authors and their organizations decided to conduct a survey of Medical and Pharmacy Directors involved with Pharmacy & Therapeutics (P&T) Committees on their policies regarding:
  - Specialty Pharmacy products
  - Use of Specialty Pharmacies
  - Expectations for biosimilar use and savings
  - Prescribers and member biosimilar education

OBJECTIVES

- To gain a better understanding of health plan management of SPs, SP products, and biosimilars today and compare with prior surveys
- The survey focused on:
  - Top SP products and co-pays
  - Biosimilar coverage, co-pays, and expected savings over time
  - Expectations for prescribers and member biosimilar education

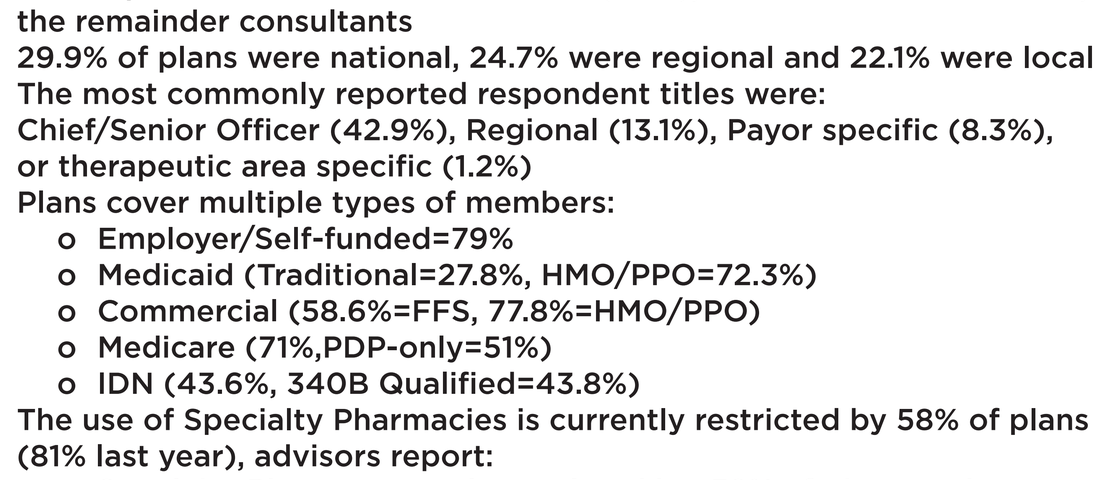
METHODS

- An online, interactive survey was developed with 79 questions
- Invitations to participate were sent to Medical and Pharmacy Directors working with US health plans, Pharmacy Benefit Managers (PBMs), and insurers from the TPG-NPRT database in November 2018
  - Material or financial incentives were not offered for completion of the survey
- Survey responses were compared with prior surveys and changes ≥2% are reported
- Survey invitations were received and reviewed by 665 managed care decision-makers

RESULTS

- A total of 85 respondents (12.8% response rate) completed the survey, some questions were not answered by all respondents
- 36.9% worked for health plans, 13.1% PBMs, 9.5% Integrated Delivery Networks (IDNs), 2.4% for Preferred Prescriber Organizations (PPOs) or Independent Provider Associations (IPAs), 1.2% for the Government, the remainder consultants
- 29.9% of plans were national, 24.7% were regional and 22.1% were local
- The most commonly reported respondent titles were: Chief/Senior Officer (42.9%), Regional (13.1%), Payor specific (8.3%), or therapeutic area specific (1.2%)
- Plans cover multiple types of members:
  - Employer/Self-funded=79%
  - Medicaid (Traditional=27.8%, HMO/PPO=72.3%)
  - Commercial (58.6%=FFS, 77.8%=HMO/PPO)
  - Medicare (71%,PDP-only=51%)
  - IDN (43.6%, 340B Qualified=43.8%)
- The use of Specialty Pharmacies is currently restricted by 58% of plans (81% last year), advisors report:
  - Specialty Pharmacy use is restricted by: 58% of plans to those under contract, 11.8% for products available through multiple SPs, 10.1% to any SP handling the product, and 4.4% carve out their SP products
  - Specialty Pharmacy Ownership: 45.6% of SPs are PBM-owned, 38.2% are health plan-owned, 23.2% are independent, and 16.1% are hospital/IDN-owned
- The top diseases treated by Specialty Pharmaceuticals are shown in Figure 1

Figure 1: Diseases Treated by Specialty Pharmaceuticals

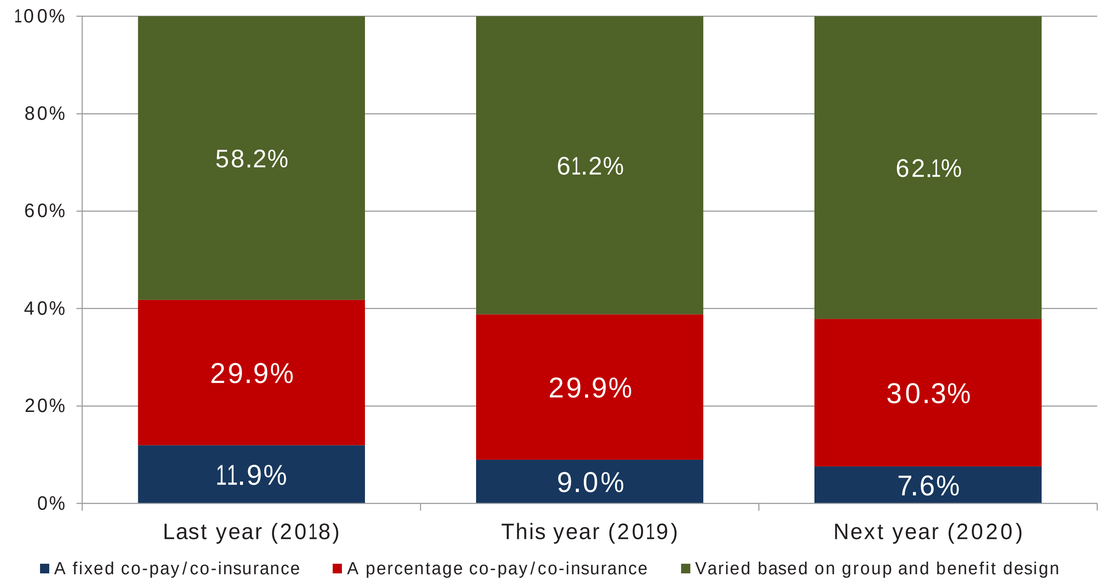


*Other included Orphan diseases, diabetes, and depends on distribution

- Plans covered clinician-administered products under the Medical Benefit (36.8%↓7.3%), 2.9% under the pharmacy benefit, the remainder used price and plan design to determine the benefit
- Specialty product co-pays continue to move from fixed to percentage with more plans using group and benefit design to determine the co-pay as shown in Figure 2

RESULTS CONTINUED

Figure 2: Co-Pay Types For Specialty Pharmacy Products



- Biosimilar use expected for all reference product indications 58.8% (↓7.3%), while 31.4% will restrict to approved indications (↓13.5%) and 9.8% will use indication as the basis for co-pay
- 10% (↓15%) of plans expect the biosimilar to be the only product available, co-pays are expected to be discounted off the innovator 58% (↓10.1%), and 32% (↓4.9%) to vary based on approval timing
- Expectations for member and prescriber education about biosimilars are shown in Figure 3
- Predicted savings from biosimilars are shown in Figure 4
- Challenges to the use of biosimilars are shown in Figure 5

Figure 3: Biosimilar Education

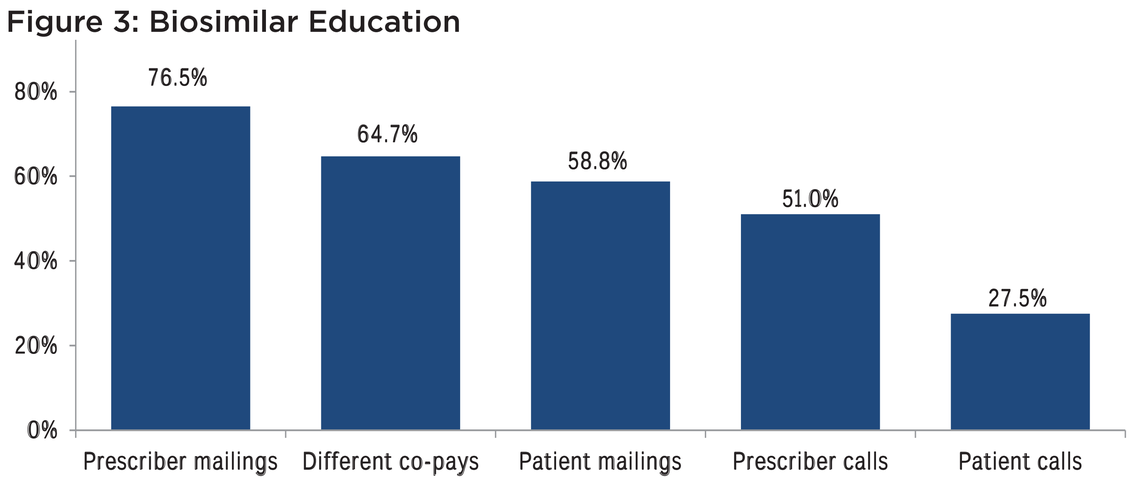


Figure 4: Predicted Savings From Biosimilars

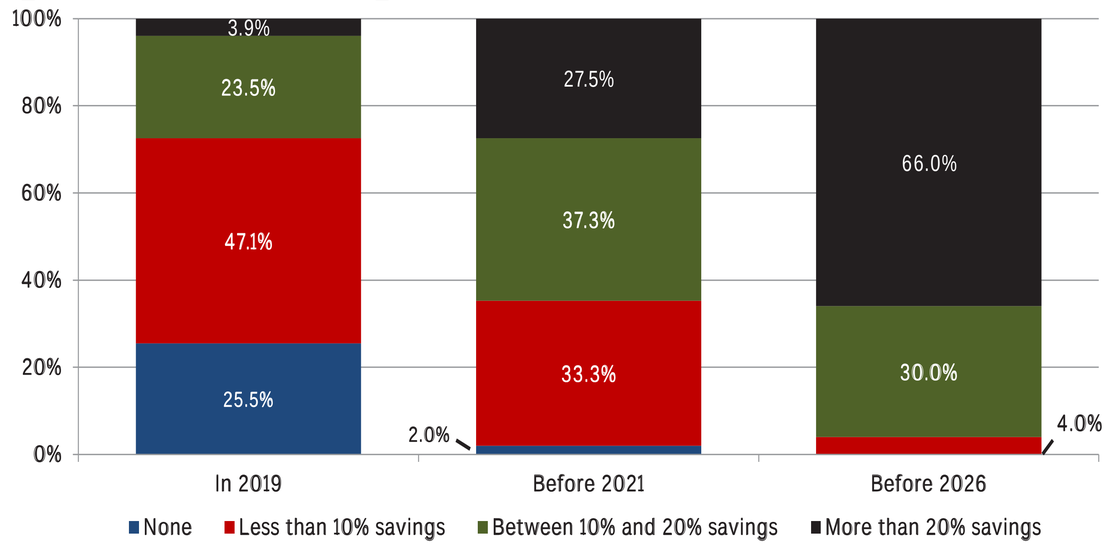
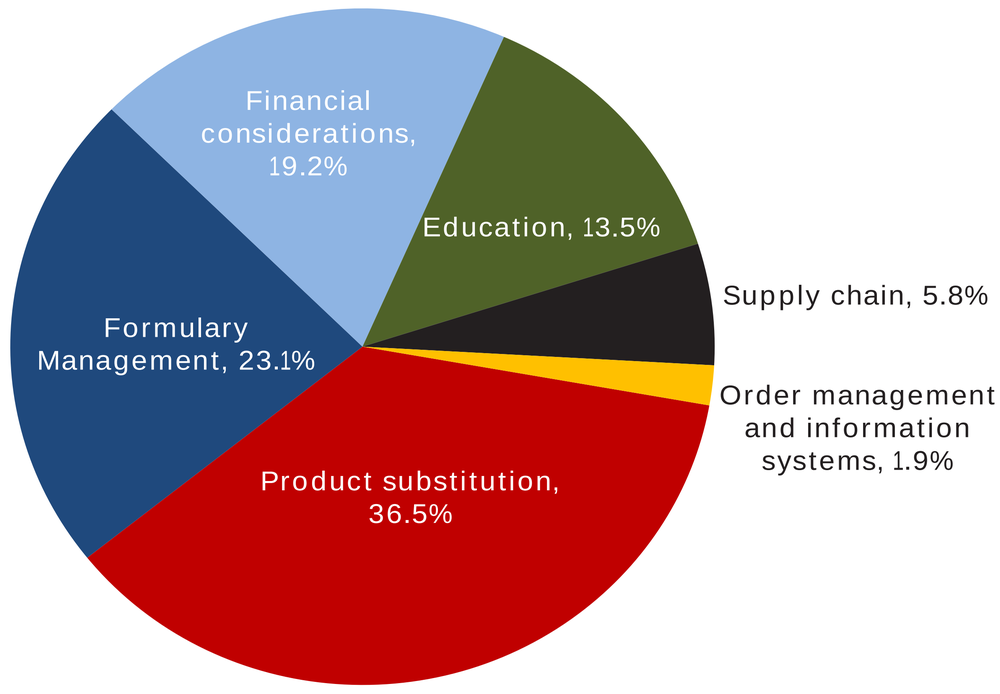


Figure 5: Operational Challenges to Use of Biosimilars



CONCLUSIONS

- Health plans' expenditures associated with Specialty Pharmacies and Specialty Pharmaceutical products have shifted and are expected to grow with some relief coming from biosimilars
- Medical and Pharmacy Directors, who commonly serve as P&T Committee members, have distinct opinions as to how to alter the process to adapt to evolving policies
- Formulary management today is changing policies on benefit design, Specialty Pharmacy products, and biosimilars to achieve optimal patient coverage at a minimum cost

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